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EXAMINER

NAFF, D

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ART UNIT	PAPER NUMBER
1808	27

DATE MAILED: 03/19/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 6/3/92 + 1/19/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 35-41 + 53-62 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 35-39 + 53-62 are rejected.

5. ☒ Claims 40 + 41 are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1808.

Note form PTO-948 in regard to the drawings attached to the office action of 5/3/91 in parent application serial no. 07/387,003 which forms this file wrapper continuation.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 35-39 and 53-62 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a buffer as required by claim 40. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The 2X storage buffer of the Cetus protocol is a buffer containing the components of claim 40. Also the specification(page 79, lines 10-14) discloses only this buffer as a specific buffer that can be used.

Claims 40 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear in requiring the buffer to comprise pH 8 since pH is not a component or substance and cannot be comprised. The buffer should be required to have a pH

of 8.

Claims 1, 35-39 and 53-59 are rejected under 35 U.S.C. § 102(a) as being anticipated by the MBR product information sheet for reasons set forth in the previous office actions of 9/4/90 and 5/3/91 in parent application serial no. 07/387,003.

Applicants have submitted a new Rule 131 Declaration to overcome defects of a Rule 131 Declaration submitted in the parent application. While the new declaration is signed by all the inventors, it fails to establish priority for other reasons set forth in the office action of 5/3/91. Furthermore, the declaration does not contain an attached letter and accompanying enclosure as stated at the end of the first paragraph on the first page. These attachments appear to be the same as contained by the previous Rule 131 Declaration submitted in the parent application and the following comments will be directed to the attachments contained by the previous declaration.

The new declaration like the previous declaration fails to establish that the non-ionic polymeric detergent alone as claimed was recognized to stabilize the thermostable nucleic acid polymerase. The enzyme diluent and 2X storage buffer of the Cetus purification protocol contain other components that could be essential for effective stability. Moreover, the enzyme diluent is being used in an assay and not for storage and has a different composition from the 2X storage buffer.

Applicants urge that nothing in the Smyczek communication(referred to on page 5 of the office action of 9/4/90 in the parent application) suggests that MBR would have used a non-ionic detergent to stabilize a purified thermostable nucleic acid polymerase composition without having first seen the Cetus protocol. However, the Goff et al patent shows using a non-ionic detergent to maintain enzyme activity and this patent supports the Smyczek assertion that the use of the detergent was obvious prior to the Wick letter. The Goff et al patent is based on an application filed in 5/6/85 which is before the Wick letter of 11/24/86. Further note the Spiegelman and Feller et al patents which disclose the presence of a non-ionic detergent during enzyme purification. The fact that MBR may not have used the detergent in a storage buffer prior to receiving the Cetus protocol could have been for reasons other than use of the detergent being unobvious in the absence of the Cetus protocol. It is clear from the patents that use of the detergent for maintaining enzyme activity was known prior to supplying MBR with the Cetus protocol.

In any event, for reasons set forth in the previous office action of 5/3/91, the MBR buffer is different from the 2X storage buffer and they are two different species of buffers. Even if after dilution, the 2X storage buffer contains essentially proportions of the MBR buffer, the 2X buffer still contains NP-40

which is not in the MBR buffer and this makes the buffers different. The 2X buffer is clearly not generic to the MBR buffer. As noted above, the enzyme diluent is being used in a polymerase assay and not as a storage buffer.

Claims 60-62 are rejected under 35 U.S.C. § 103 as being unpatentable over the product information sheet of MBR for reasons set forth in the previous office actions of 9/4/90 and 5/3/91 in the parent application.

The comments set forth above also apply to arguments concerning this rejection.

Claims 1, 35-39, 53-59 and 62 are rejected under 35 U.S.C. § 103 as being unpatentable over Kaledin et al(1980) in view of Goff et al and, if necessary, in further view of Feller et al or Spiegelman for reasons set forth in the previous office actions of 9/4/90 and 5/3/91 in the parent application .

The Rule 132 Akers Declaration is unpersuasive. In experiment 1, it is unclear as to what is considered to be the "functionality" that the non-ionic detergent has no effect on. Is this functionality, activity, or some other property? If the functionality is activity, then this result conflicts with the Goff et al reference which discloses that a non-ionic detergent prevents loss of activity. There is seen no reason to accept this declaration result as correct and the result of Goff et al as incorrect. The result of experiment 2 would have been

expected since Goff et al suggest that a non-ionic detergent is prevents loss of activity. Moreover, this experiment used NP-40 and Tween 20 in combination which the present claims do not require. Similarly, in experiment 3, both NP-40 and Tween 20 were present together which the claims do not require. Additionally, in all the experiments, a standard buffer of a certain pH was used that contained substances not required by the present claims.

The Rule 132 Declaration of Gelfand is unpersuasive since there is seen nothing to support that a difference in amino acid sequence and isoelectric point influences how a non-ionic detergent effects enzyme activity.

Claims 60 and 61 are rejected under 35 U.S.C. § 103 as being unpatentable over the references as applied to claims 1, 35-39, 53-59 and 62 above, and further in view of Kaledin et al(1981) for reasons set forth in the previous office actions in the parent application.

Comments set forth above in response to applicants' arguments also apply to this rejection.

Claims 40 and 41 are free of the prior art.

The references have been previously made of record on form PTO-892 or -1449 in parent application serial no. 07/387,003 which forms this present file wrapper continuation.

Any inquiry concerning this communication should be directed

to Examiner Naff at telephone number (703) 308--0520.

DMN
July 13, 1992

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 182